

Claims

What is claimed is:

- 5 1. A method of administering a growth hormone secretagogue to a patient, the method comprising the step of intermittently administering to a patient in need of growth hormone secretagogue administration a therapeutically effective amount of a growth hormone secretagogue.
- 10 2. The method of claim 1 wherein the patient is a human.
3. The method of claim 1 wherein the growth hormone secretagogue is administered every second day.
- 15 4. The method of claim 1 wherein the growth hormone secretagogue is administered every third day.
5. The method of claim 1 wherein the growth hormone secretagogue is administered every fourth day or every fifth day.
- 20 6. The method of claim 1 wherein the growth hormone secretagogue is administered three times a week.
7. The method of claim 1 wherein the growth hormone secretagogue is administered four times a week.
- 25 8. The method of claim 1 wherein the growth hormone secretagogue is administered orally.
- 30 9. The method of claim 1 wherein the growth hormone secretagogue is administered using an immediate release formulation.
10. The method of claim 1 wherein the growth hormone secretagogue is administered using a controlled release formulation.

11. The method of claim 9 wherein the controlled release formulation is a sustained release formulation, a delayed release formulation, or a combination thereof.

5 12. The method of claim 1 wherein the growth hormone secretagogue is administered using a combination of immediate release and controlled release formulations.

10 13. The method of claim 1 wherein the growth hormone secretagogue is 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide or a pharmaceutically acceptable salt or prodrug thereof, or a salt of the prodrug.

15 14. The method of claim 1 wherein the growth hormone secretagogue is 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide L-tartrate.

20 15. The method of claim 1 wherein the growth hormone secretagogue is 2-amino-N-{1-(R)-(2,4-difluoro-benzyloxymethyl)-2-oxo-2-[3-oxo-3a-(R)-pyridin-2-ylmethyl-2-(2,2,2-trifluoro-ethyl)-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl]-ethyl}-2-methyl-propionamide or a pharmaceutically acceptable salt or prodrug thereof, or a salt of the prodrug.

25 16. The method of claim 1 wherein the growth hormone secretagogue is the (L)-(+)-tartaric acid salt of 2-amino-N-{1-(R)-(2,4-difluoro-benzyloxymethyl)-2-oxo-2-[3-oxo-3a-(R)-pyridin-2-ylmethyl-2-(2,2,2-trifluoro-ethyl)-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl]-ethyl}-2-methyl-propionamide.

30 17. The method of claim 1 wherein the growth hormone secretagogue is administered using a tablet or capsule.

18. The method of claim 1 wherein the growth hormone is administered once, twice or three times daily on the days of administration.

19. A method of administering 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-
2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-
ethyl]-isobutyramide L-tartrate to a patient in need thereof, the method comprising the
step of intermittently administering a therapeutically effective amount of 2-amino-N-
5 [2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-
1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide L-tartrate.

20. The method of claim 19 wherein the patient is a human.

10 21. The method of claim 19 wherein 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-
2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-
ethyl]-isobutyramide L-tartrate is administered every second day.

15 22. The method of claim 19 wherein 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-
2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-
ethyl]-isobutyramide L-tartrate is administered every third day.

20 23. The method of claim 19 wherein the 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-
oxo-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-
ethyl]-isobutyramide L-tartrate is administered orally in a tablet or capsule.

25 24. The method of claim 19 wherein 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-
2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-
ethyl]- isobutyramide L-tartrate is administered in an amount in the range of about 1
mg to about 10 mg per day on the days of administration.

30 25. The method of claim 19 wherein the intermittent administration of 2-amino-N-[2-
(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-
(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide L-tartrate results in a peak plasma
concentration in humans of growth hormone of about 5ng/ml or greater.

26. The method of claim 1 wherein the patient is obese or has musculoskeletal
frailty, osteoporosis, congestive heart failure or insulin resistance.

27. A kit that comprises:

- a. a composition comprising a growth hormone secretagogue;
- b. a package for containing the composition; and
- c. instructions for intermittently administering the composition comprising the growth

5 hormone secretagogue.

28. The kit of claim 27 wherein the growth hormone secretagogue is 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide L-tartrate.

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29. The kit of claim 27 that further comprises, in addition to a growth hormone secretagogue, an additional compound that can be used to treat obesity, musculoskeletal frailty, osteoporosis, congestive heart failure or insulin resistance.

15 30. The kit of claim 27 wherein the composition comprising a growth hormone secretagogue is a tablet or capsule.

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